UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
EPA SCIENCE ADVISORY BOARD

October 22, 2002

MEMORANDUM

SUBJECT: US EPA Science Advisory Board (SAB) Human Health Research Strategy Review Panel (HHRS Review Panel) – Documentation for Panel Formation Determinations

FROM: Sue Shallal, Ph.D. ***/ Signed /***
Designated Federal Officer
EPA Science Advisory Board Staff Office (1400A)

TO: Robert Flaak
Acting Deputy Director
EPA Science Advisory Board Staff Office (1400A)

This memo addresses the set of determinations that are necessary for starting a review by the SAB. It provides background information on this SAB review activity and then addresses:

1) the charge developed for the panel;
2) the type of Panel that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair; the types of expertise needed to address the charge;
3) identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
4) whether the charge involves a Particular Matter and how conflict of interest regulations under 18 U.S.C. 208. apply to members of the panel;
5) how regulations concerning "appearance of lack of impartiality" under 5 C.F.R. 2635.502 apply to members of the panel;
6) how individuals were placed on the "Short List" posted on the SAB website as candidates for the panel; and
7) how individuals were placed on the final panel.

This memo serves to document the status of decisions on each of these topics and to document the OSAB Deputy Director's approval of those decisions.

A. Background

The EPA Science Advisory Board was asked by the Office of Research and Development (ORD) to peer review a draft document "Human Health Research Strategy for improving Risk Assessment." A request for nominations for the peer review panel appeared in the *Federal Register* on June 19, 2002 (67 FR 41718-41721; See Attachment 1).

In the Federal Register (FR) notice the Board noted this background: The Human Health Research Strategy presents the strategic directions for ORD's core research program in human health risk assessment over the next five to ten years. The research directions are based on the evaluation of research needs from the Agency's regulatory and regional programs and consideration of recommendations by external advisory groups. The research strategy discusses the major environmental problems, the principal scientific issues, and priority research areas that need to be addressed to resolve the problems. The strategy document also describes the research approach and expected impact that the research will make to strengthen the scientific foundation for human health risk assessments across EPA. The strategy does not describe ORD's entire research program on human health; rather, only that portion for which the results will have broad Agency applicability. Efforts are made in the document to cross link other ORD media-specific or problem-driven research programs.

ORD's strategic research directions for Human Health include 1) research to improve the scientific foundation of human health risk assessment; and 2) research to enable evaluation of public health outcomes from environmental risk management decisions.

B. Determinations

1) The charge to the panel: SAB Staff, Deputy Director of the SAB and the Agency negotiated the following charge:

> a) Does the document establish the appropriate direction and research areas (i.e., aggregate-cumulative risk, harmonization, susceptible subpopulations, effectiveness of public health outcomes) for a long-term, core research program on human health risk assessment;
> b) Will the research that is described reduce uncertainty in the risk assessment process;
> c) For the research areas selected, does the strategy provide a clear framework for a multi disciplinary research program;
> d) Does the strategy provide a logical approach for framing research to evaluate the impact of risk management decisions on human health?

2) Type of Panel that will be used to conduct the review, the name of the Panel, and identification of the Panel Chair; types of expertise needed to address the charge: An ad-hoc panel of the SAB's Executive Committee (EC) called the "Human Health Research Strategy Review Panel" will conduct the review. A broad base of expertise was needed to review this

document due to the fact that it deals with a wide range of topics associated with improving human health risk assessment. The SAB, in its June 2002 FR Notice cited above solicited nominations for experts to address the HHRS document. In the FR notice, the Board requested nominations in the following areas: Risk assessment and the application of the Agency's risk assessment guidelines; Exposure measurement/assessment; Dosimetry/mechanisms of action; Aggregate and cumulative risk; Computational toxicology; Research into various toxicologic endpoints including carcinogenicity; Molecular genetics; Epidemiology; Health effects in sensitive and population groups; Uncertainty analysis; and Public health outcomes.

3) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: Interested parties are those who follow risk assessment developments and EPA's implementation of new risk assessment approaches (i.e., The regulated community, public interest groups, those interested in alternative testing methods, and others).

4) Whether the charge involves a Particular Matter[1] and how conflict of interest regulations apply to members of the panel: In consultation with EPA Senior Ethics Counsel, it was determined that the SAB panel's activity in addressing the charge does qualify as a particular matter because the advice that will result will be part of a deliberation, in that the Federal Experts or Special Government Employees (SGE), who are serving on the panel, will be providing advice that will be considered in the course of the Agency's deliberation about the ORD's Human Health Research Strategy. This information may influence ORD's research priorities and may divert funding to different areas. Although the review, does not focus on the interests of specific people (i.e., it is not a "specific party matter"), it does arguably focus on the interest of a discrete and identifiable class of people, i.e., those who may receive funding from this research strategy.

In order to determine how conflict of interest regulations apply to members of the panel, the DFO conducted an analysis for each panel member to determine whether the following provision of 18 U.S.C. 208 applies: "An employee is prohibiting from participating personally and substantially in an official capacity in any particular matter in which he, to his knowledge, he or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest."

For this review, the DFO assumes generally that the panel members will be participating personally in the review and that they will be participating substantially. Following standard procedures, the DFO determines, on a case-by-case basis whether the panel member knows of any financial interest in this matter on the part of the SGE; the SGE's spouse or minor child; a general partner; an organization in which the SGE is serving as an officer, director, trustee, general partner, or employee; or a prospective employer. The DFO has determined through

[1]The term "particular matter" refers to matters that involve deliberation, decision, or action that is focused on the interests of specific people or a discrete and identifiable class of people. The term may include matters that do not involve formal parties and may extend to legislation or policy-making that is narrowly focused on the interests of a discrete and identifiable class of people. But the term does not cover consideration or adoption of broad policy options directed to the interests of a large and diverse group of people. [5 C.F.R. 2640.103(a)(1)]

review of all Confidential Financial Disclosure Reports provided by all prospective panelists that there is no conflict of interest presented. The DFO assumes generally for this review that the panel's advice on the particular matter under review will not have a direct effect on the financial interest of panelists.[2]

5. How regulations concerning "appearance of lack of impartiality" under 5 C.F.R. 2635.502 apply to members of the panel. The Code of Federal Regulations state that "Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee."

The HHRS review activity is not a specific party matter, so there is no legal issue concerning "conflict of interest" under federal regulations. Additionally, in an effort to be responsive to the concerns of interested parties, we have attempted to select individuals that represent varying points of view to minimize issues regarding "lack of impartiality". Panelists have backgrounds that include experience with industry, academia, federal and state agencies, as well as, consultant groups. We have also precluded individuals who receive research funding from EPA's Office of Research and Development and which is directly linked to improving human health risk assessment.

6. How individuals were selected for the "Short List" posted on the SAB website as candidates for the panel. In August 2002, the SAB Staff posted a notice on the SAB website inviting comment on Prospective Candidates for the HHRS Review Panel (Attachment 2). That notice stated that SAB staff narrowed a "Widecast" list of candidates to a "Short List" of 28 candidates, based upon their expertise, interest, availability, and credentials. SAB Staff also took care to include individuals with knowledge of the risk assessment process but who had not previously been involved with the design of this research strategy. SAB Staff defined "involvement"in this case as: no authorship of the document, collaboration with the authors, prior peer review, or authorship of public comments on the document.

7. How individuals were selected for the final panel. The SAB received two sets of public comments in response to its request for "information, analysis, or documentation" that the Board should consider in making its selection of members of the panel. (Attachment 3 lists the

[2]A particular matter has a direct effect on a financial interest if a close causal link exists between any decision/action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter does not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect. 5 C.F.R. 2640.103(a)(3)(i).

names of groups and individuals submitting public comment). These requests were received by the time the public comment period closed on September 16, 2002.

SAB Staff considered this information along with: (a) the Confidential Financial Disclosure Forms (EPA form 1130-48) completed by all Short List Candidates; (b) responses from Short List candidates to queries about their "points of view" and relationship to the review material to be considered by the panel (Attachment 4); and (c) *Curriculum Vitae* provided by candidates and supplementary materials provided by them. In reviewing final panel membership, the need for experts in the areas of exposure modeling and exposure assessment was established; therefore, the short list was supplemented by two current SAB members who possess these qualifications.

Since this review concerns a research strategy developed by the EPA's Office of Research and Development, we attempted to minimize any conflict of interest by selecting only individuals who do not currently receive funding from EPA sources that may be linked to the review in question. In addition to these considerations and those listed above, SAB Staff developed a list of the potential panelists. Based on availability and continued interest; a panel of 13 experts were selected.

1. Dr. James Klaunig, Indiana University (Chair)
2. Dr. Paul Blanc, University of California San Francisco
3. Dr. James Gibson, East Carolina University
4. Dr. Michael Jayjock, Rhom and Haas Co
5. Dr. George Lambert, University of Medicine and Dentistry of New Jersey
6. Dr. Joseph Landolph, University of Southern California
7. Dr. Steve Lewis, Exxon Mobil Biomedical Sciences, Inc
8. Dr. Randy Maddalena, Lawrence Berkeley National Lab
9. Dr. Maria Morandi, University of Texas Houston Health Sciences Center
10. Dr. Beate Ritz, University of California Los Angeles
11. Dr. Herbert Rosenkranz, Florida Atlantic University
12. Dr. Robert Spengler, ATSDR
13. Dr. Bernard Weiss, University of Rochester Medical Center

Concurred,

/ Signed /

Robert Flaak
Acting Director
EPA Science Advisory Board Staff

October 22, 2002
Date

Attachment 1: *Federal Register* Request for Nominations for the HHRS panel, June 19, 2002 (67 FR 41718-41721)
Attachment 2: Invitation for Comment on Prospective Candidates to the HHRS Review Panel
Attachment 3: List of the Names of Groups and Individuals Submitting Public Comment on the HHRS Short List
Attachment 4: Questions posted to Short List candidates about their "points of view" and relationship to the review material to be considered by the panel
Attachment 5: Roster of individuals selected for the Panel

Attachment 1

ENVIRONMENTAL PROTECTION AGENCY
EPA Science Advisory Board
Human Health Research Strategy Review Panel
Request for Nominations

Action: Notice; request for nominations to serve on the Human Health Research Strategy Review Panel (HHRS Review Panel) of the U. S. Environmental Protection Agency's Science Advisory Board (SAB).

Summary: The U.S. Environmental Protection Agency's (Agency, EPA) Science Advisory Board (SAB) is announcing the formation of a panel to review the Agency's *Human Health Research Strategy* and the solicitation of nominations for qualified individuals to serve on this Panel. To establish this panel, the SAB is soliciting nominations to augment a pool of candidates now composed of its existing Environmental Health Committee (EHC) and its Integrated Human Exposure Committee (IHEC). The EPA Science Advisory Board was established to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA regulations. In this sense, the Board functions as a technical peer review panel for the research strategy.

For Further Information - Additional information on this review can be obtained by contacting Mr. Thomas O. Miller, Designated Federal Officer, Human Health Research Strategy Review Panel, US EPA Science Advisory Board (1400A), Suite 6450CC, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone/voice mail at (202) 564-4558; fax at (202) 501-0582; or via e-mail at miller.tom@epa.gov.

Nomination information should be submitted via email (preferred) to Ms. Diana Pozun, Management Assistant, EPA Science Advisory Board, U.S. Environmental Protection Agency (1400A), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460, telephone (202) 564-4544; FAX (202) 501-0323, email pozun.diana@epa.gov.

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (http://www.epa.gov/sab) and in the *Science Advisory Board FY2001 Annual Staff Report* which is available from the SAB Publications Staff at (202) 564-4533, via fax at (202) 501-0256, or on the SAB Website at http://www.epa.gov/sab/annreport01.pdf.

Nomination Procedures: The approved policy under which the EPA Science Advisory Board establishes review panels is described in a recent Commentary, *EPA Science Advisory Board (SAB) Panel Formation Process: Immediate Steps to Improve Policies and Procedures: An SAB Commentary* (EPA-SAB-EC-COM-002-003), which can be found on the SAB website at www.epa.gov/sab/ecm02003.pdf. Principles discussed in that document will govern the establishment of the HHRS Review Panel.

Any interested person or organization may nominate qualified individuals for membership on the HHRS Review Panel. Nominations, preferably in electronic format, should be submitted to Ms. Pozun at pozun.diana@epa.gov. Anyone unable to submit nominations in

electronic format should send the information specified below to Ms. Pozun (address above) Nominations should arrive no later than (**enter the date 15 calendar days after the publication date of this notice)**, 2002. The Agency will not necessarily formally acknowledge or respond to nominations.

Nominations must include the individual's name, occupation, position, qualifications to address the issue, and contact information (i.e., telephone number, fax number, mailing address, email, and/or Website). To be considered, all nominations must include a current biographical sketch (approximately one page in length), CV or resume (preferably electronic in MSWord or WordPerfect) providing information on the nominee's background, experience, and qualifications for this Panel. Detailed information on the nominator is not required, but the nominator's name, affiliation, and contact information is requested in order to permit the staff to contact the nominators with any questions and keep them informed of activities associated with this review. Names and affiliations of nominators for individuals on the "Short List" that the SAB intends to consider further for panel membership, will be included in the information made available to the public when the Short List is announced.

To improve the efficiency in processing of nominations the SAB requests that nominations be provided in the following manner:

(1) Send the nomination by email to: pozun.diana@epa.gov
(2) Use one email per person being nominated
(3) Please use "Human Health Research Strategy Nomination" in the subject field, followed by the last name of the candidate you are nominating. (For example, "Human Health Research Strategy Nomination: Smith)
(4) Attach supporting information in MS Word or Wordperfect files ending in ".doc" or ".wpd", respectively
(5) In a separate file from the biographical sketch, CV or resume, please provide the following information in the order shown:

<u>For the Nominating Individual</u>
First Name:
Last Name:
Organizational Affiliation and Title:
Email Address:
Mailing Address:
Work Phone:
Work Fax:

<u>For the Candidate being nominated:</u>
First Name:
Last Name:
Professional Title:
Department:
School or Unit:
University or Organization:
Mailing Address:
Work Phone:
Fax Work Phone:

Email Address:
Website for CV (if one exists):

Nominator's Assessment of Expertise:
The following areas of expertise will be useful in this review. Please indicate the areas of expertise the candidate could contribute with a short statement explaining why this is the case:

1. Risk assessment and the application of the Agency's risk assessment guidelines;
2. Exposure measurement/assessment;
3. Dosimetry/mechanisms of action;
4. Computational toxicology;
5. Aggregate and cumulative risk;
6. Research into various toxicologic endpoints including carcinogenicity;
7. Molecular genetics;
8. Epidemiology;
9. Health effects in sensitive and susceptible population groups;
10. Uncertainty analysis; and
11. Public health outcomes
12. Others that nominators might feel to be appropriate

Evaluation Procedures: **Evaluation Procedures**: The SAB panel formation process, mentioned earlier in this notice, is described in an SAB Commentary, *EPA Science Advisory Board (SAB) Panel Formation Process: Immediate Steps to Improve Policies and Procedures: An SAB Commentary* (http://www.epa.gov/sab/ecm02003.pdf). This process guides the activity used by the SAB to gather and evaluate nominees and to select a panel having balanced membership. At the SAB, a balanced panel is characterized by inclusion of the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors can be influenced by work history and affiliation), and the collective breadth of experience to address the charge adequately.

First, the process solicits nominations to the Panel from SAB members and consultants, external outreach to the public, and contact with the Agency itself to obtain a broad set of nominees to consider for membership. Second, the nominations received are combined and entered into a data base termed the "WIDECAST." Third, a smaller subset (the "Short List") will be identified from this larger group of nominees for more detailed consideration. The Short List includes the names of candidates, a short biographical sketch of each candidate, and the names of those who nominated the person. Fourth, the Short List is posted on the SAB Website (www.epa.gov/sab), and public comments accepted on the individual's expertise, conflict-of-interest, questions on any perceived lack of impartiality of the person (as defined by federal regulation), as well as on the overall balance of technical views represented on the Panel.

Finally, the Panel members are selected by considering public reaction to the Short List candidates, information provided by candidates, and information on the background of each candidate which is gathered independently by SAB Staff. Criteria used in the evaluating of individual panelists include: a) expertise, knowledge, and experience (primary factors); b) scientific credibility and impartiality; c) skills working in committees and advisory panels; and d) availability.

Panel members will be asked to attend at least one public face-to-face meeting and,

probably, several public telephone conference call meetings over the anticipated 3-month course of the activity. The Executive Committee (EC) of the SAB will review the Panel's report in a public meeting and reach a judgment about its transmittal to the Administrator.

Background: The mission of the U.S. Environmental Protection Agency (EPA) is to protect public health and safeguard the natural environment. Risk assessment is an integral part of this mission in that it identifies and characterizes environmentally related human health problems. The *Human Health Research Strategy* document presents a conceptual framework for future human health research by EPA's Office of Research and Development (ORD). The Agency's research strategy outlines a core research effort to provide broader, more fundamental information that will improve understanding of problem-driven health risk issues encountered by the EPA's Program and Regional Offices. The document focuses on broad themes and general approaches. Implementation of an integrated research program on human health is described in greater detail in ORD's Multiyear Plan on Human Health Research which identifies the specific performance goals and the measures needed to achieve those goals over a 5 to10 year period.

ORD's strategic research directions for Human Health include 1) research to improve the scientific foundation of human health risk assessment; and 2) research to enable evaluation of public health outcomes from environmental risk management decisions.

1. Research to Improve the Scientific Foundation of Human Health Risk Assessment. ORD's human health risk assessment program assumes that major uncertainties in risk assessment can be reduced by understanding and elucidating the fundamental determinants of exposure and dose and the basic biological changes that follow exposure to pollutants and which result in a toxic response. This research will provide the scientific knowledge and principles to improve the risk assessment for all human health endpoints, aggregate and cumulative risk, and risk to susceptible populations.

One component of this forward looking research focuses on **Harmonizing Risk Assessment Approaches**. This research addresses the differing approaches for the assessment of risk from cancer and noncancer health endpoints. The intent of this research is to develop a common set of principles and guidelines for drawing inferences about risk based on mechanistic information. Specific research objectives include: i) the development of emerging technologies or methods to study mode or mechanism of action; ii) provision of a framework for defining mode or mechanism of action; iii) development of a basis for comparing risk across all health endpoints using mechanistic information; iv) developing principles for the use of mechanistic data to select the most appropriate risk assessment model; and v) development of principles for the use of mechanistic data to reduce or replace uncertainty factors in risk assessments, especially for inter- and intraspecies extrapolation.

Research on **Aggregate and Cumulative Risk** reflects the reality that humans are exposed to mixtures of pollutants from multiple sources. This research will provide the scientific support for decisions concerning exposure to a pollutant by multiple routes of exposure or to multiple pollutants having a similar mode of action. ORD will also develop approaches to study how people and communities are affected following exposure to multiple pollutants that may interact with other environmental stressors. Specific research objectives include: i) determining the best and most cost-effective ways to measure human exposures in all relevant media; ii) developing exposure models and methods suitable for the EPA and the public to assess

aggregate and cumulative risk; and iii) providing the scientific basis to predict the interactive effects of pollutants in mixtures and the most appropriate approaches for combining effects and risks from pollutant mixtures.

Research on **Susceptible and Highly-Exposed Subpopulations** will focus on developing a scientific understanding of the biological basis for differing responsiveness of subpopulations within the general population. Specific research objectives include the following: i) identifying the key factors that contribute to variability in human exposure; ii) improving the accuracy of dose estimation in the general population; iii) identifying the biological basis underlying differential responsiveness of sensitive subpopulations of humans to pollutant exposure; and iv) determining how exposure, dose and effect information can be incorporated into risk assessment methods to account for interindividual variability.

2. Research to Enable Evaluation of Public Health Outcomes from Risk Management Actions

Generally, the EPA has not prepared retrospective evaluations to determine if the intended public health protection benefits were realized once an EPA decision had been in place for a period of time. With the advent of the Government Performance and Results Act (GPRA) and calls for the EPA to stress and demonstrate outcome-oriented goals and measures of success, research is needed to enable evaluation of actual public health outcomes from risk management actions. Estimating public health benefits of EPA regulatory decisions and rule making, or in a more general sense evaluating public health outcomes from risk management actions, will involve a number of disciplines grounded in both the physical and social sciences, and increasingly must take into account the economic and behavioral aspects of human decision-making.

The long term goal of ORD's research on public health outcomes is to provide the scientific understanding and tools for use in evaluating the effectiveness of public health outcomes resulting from risk management actions. Research will focus on identifying, discovering, or developing the most effective methods and models; determining how they can be integrated into a decision-making framework to assist Federal, State, and local decision-makers in evaluating changes in public health as a result of risk management actions; and developing a framework to quantify such changes accurately. Specific research objectives include: i) establishing the linkage between sources, environmental concentrations, exposure, adverse effects or disease, and effectiveness so that a change in a human health outcomes subsequent to a risk management action can be determined by measuring or modeling any one of these linked steps; and ii) improving methods and models by which others can measure or model changes in public health outcomes following various risk management actions.

Charge: The current Charge that the Agency is asking the SAB to implement in this review follows. The final Charge may change some as a result of ongoing discussions between the Agency and the Panel. Updates will be posted on the SAB Website: www.epa.gov/sab.

ORD is requesting a review by the SAB of the Human Health Research Strategy, including the following points:

a. Does the document establish the appropriate direction and research areas (i.e.,

aggregate-cumulative risk, harmonization, susceptible subpopulations, effectiveness of public health outcomes) for a long-term, core research program on human health risk assessment?

b. Will the research that is described reduce uncertainty in the risk assessment process?

c. For the research areas selected, does the strategy provide a clear framework for a multi-disciplinary research program?

d. Does the strategy provide a logical approach for framing research to evaluate the impact of risk management decisions on human health?

Review Document Availability - The EPA research strategy for human health is documented in the *Human Health Research Strategy*, U.S. EPA Office of Research and Development, Internal Review Draft, May 2002. Those members of the public who wish to view the Agency draft document as they consider who might be appropriate to nominate for this panel should obtain or read it on the EPA ORD NHEERL website at www.epa.gov/nheerl/humanhealth. The public may also contact Dr. Hugh Tilson, National Health and Environmental Effects Research Laboratory by voice telephone at (919) 541-4607; fax at (919) 685-3252; or mail at Dr. Hugh Tilson, Associate Laboratory Director, NHEERL, Mail Code B30502, Research Triangle Park, NC 27711.

_____ _____

Date

A. Robert Flaak

Acting Deputy Director

EPA Science Advisory Board.

Attachment 2

Invitation for Comments on Prospective Candidates for the EPA Science Advisory Board's Human Health Research Strategy Review Panel

October 7-9, 2002 Availability

The EPA Science Advisory Board (SAB, Board) announced in 67 FR 41718-41721, June 19, 2002 that it had been asked to undertake a review of EPA's draft *Human Health Research Strategy*. The background, charge, and description of the document to be reviewed appear in the above referenced Federal Register notice and are also available at the SAB website (www.epa.gov/sab).

The Board invited nominations for the panel being formed. The SAB's process for panel formation – approved by the Executive Committee May 8, 2002 – has been designed for three purposes:

a. to help the Board meet EPA's legal requirements;

b. to be transparent to the public, so the public can understand and participate in the process; and

c. to help the Board fulfill its mission.

Individuals and organizations provided nominees in response to the Federal Register notice; and the Agency, SAB members and SAB staff provided additional names.

The list of nominees has been narrowed down to a "Short List" of 28 candidates based on expertise, interest, availability, and the timely provision of information for the biosketches provided below. We invite comments from the public on these candidates. We welcome information, analysis or documentation that the Board should consider in evaluating the remaining candidates. This information will be carefully considered in selecting the panel. Normally the SAB Director, in consultation with SAB leadership, as appropriate makes the final decision about who will serve on the panel. Because the current SAB Director was involved with the development of the document under review, the Acting Deputy Director will make those decisions instead. During Panel Selection, the SAB Staff completes its review of information regarding conflict of interest, possible appearance of impartiality, and appropriate balance and breadth needed to address the charge. The staff reviews all the information provided by the candidates, along with any information that the public may provide in response to the posting of information about the prospective panel on the SAB website during the "Short List Phase," and information gathered by the SAB Staff independently on the background of each

candidate.

Please provide any advice, observations or comments you think would be helpful in selecting the final candidates no later than September 16, 2002. Please send your comments to the attention of Thomas Miller, Designated Federal Officer, Human Health Research Strategy Review Panel. Emailed comments are preferred (miller.tom@epa.gov). Written comments will also be accepted. Mr. Miller's mailing address is: U.S. EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

The dates for the face-to-face and telephone conference meetings on this topic will be formally announced in the *Federal Register*. These meetings will include brief presentations by EPA on the strategy, deliberations by the Panelists on the charge questions, and public comment.

Brief Biographical Sketches for the Human Health Research Strategy Panel (the "Short List")

Dr. Henry Anderson

In 1980 Dr. Anderson joined the Wisconsin Department of Health and Social Services as the State Environmental and Occupational Disease Epidemiologist. In 1991 he also assumed the duties of Chief Medical Officer. Among his duties for the State of Wisconsin has been the development of the scientific support documents for Wisconsin's Groundwater Enforcement Standards.

Dr. Anderson received his MD degree in 1972 and entered an Internal Medicine internship and then an occupational medicine residency. He was certified in 1977 by the American Board of Preventive Medicine with a sub-specialty in occupational and environmental medicine and in 1983 became a fellow of the American College of Epidemiology. He holds adjunct Professorships at the University of Wisconsin-Madison, Department of Preventive Medicine and the University of Wisconsin Institute for Environmental Studies, Center for Human Studies. He has published over 160 scientific articles on a broad spectrum of environmental, occupational, and public health topics. He is principal investigator on nine active grants and cooperative agreements from federal government agencies including the Us EPA. Dr. Anderson's US EPA funded research grants address children's health issues, such as reproductive and endocrine function of frequent Great Lakes sport fish consumers and evaluation of women's awareness of mercury toxicity and sport fish consumption advisories. Other current research includes: childhood asthma, lead poisoning, arsenic in drinking water, youth occupational health, occupational fatalities and bio-terrorism response. His expertise includes public health, preventive/environmental/occupational medicine, respiratory diseases, epidemiology, human health risk assessment and risk communication.

Dr Anderson was a founding member of the Agency for Toxic substances and Disease Registry (ATSDR) Board of Scientific Counselors (1988-1992). He served on National Academy of Sciences/Institute of Medicine (NAS/IOM) committees that developed the reports "Injury in America" and Nursing, Health & Environment." He was a member of the Armed Forces Epidemiology Board. He is currently Chair of the Environmental Health Committee of the US EPA Science Advisory Board and Past Chair of the Integrated Human Exposure Committee. He serves on the USEPA SAB Executive Committee. He serves on several other FACA committees including the Director's Advisory Board for the National Center for Environmental Health, Centers for Disease Control and Prevention, the Hanford Health Effects Subcommittee for ATSDR and is a member of the NIOSH Advisory Board on Radiation and Worker Health. He is a fellow of the Collegium Ramazzini and the American Association for the Advancement of Science. He is associate editor of the *American Journal of Industrial Medicine* and serves on the editorial board of *Cancer Prevention International.*

Neal D. Barnard, M.D.

Dr. Barnard is President of the Physicians Committee for Responsible Medicine. He holds a degree as a Doctor of Medicine from the George Washington University School of Medicine and a B.A. from MacAlester College. Dr. Barnard□s expertise is in epidemiology, study

design, animal welfare. His Research Activities involved randomized clinical trials and nutrition reviews. He has served on a number of advisory committees, professional societies associated with issues under discussion in this review. Dr, Barnard ▽ s recent grant and/or contract support comes from the Diabetes Action Research and Education Foundation

Dr. Paul Blanc

Dr. Blanc is a Professor of Medicine and Endowed Chair for Occupational Medicine as well as Chief of the Division of Occupational and Environmental Medicine at the University of San Francisco (Pa rnassus Heights Campus). Dr. Blanc holds a MD degree from the Albert Einstein College of Medicine and also holds a Masters of Science in Public Health in Industrial Hygiene from the Harvard School of Public Health. He is trained in occupational medicine and internal medicine and also holds a certificate of added qualifications in medical toxicology. He is a former Robert Wood Journal Clinical Scholar and a Fulbright Senior Research Fellow. Dr. Blanc's research interests include asthma and COPD in relation to workplace and environmental factors and occupational and environmental toxicology, especially in terms of pulmonary responses.

Dr. Susan Borgoff

Dr. Borghoff has been a Staff Scientist at CIIT Centers for Health Research in the Research Triangle Park, North Carolina since 1989 following her postdoctoral fellowship. Dr. Borghoff received her Ph.D. and MSPH in Environmental Sciences and Engineering from the University of North Carolina, and a B.S. in Chemistry from East Stroudsburg University in Pennsylvania. Dr. Borghoff became a Diplomat of the American Board of Toxicology in 1994. Along with Dr. Borghoff's research program at CIIT she is also the Director of Education Programs which involves oversight of the pre- to post- graduate training programs and K-12 educational outreach activities. Her research interests have focused on understanding the modeof-

action by which specific chemicals cause kidney toxicity and cancer in rats with a view to understanding the relevance of this response for human risk assessment. Her research has also focused on understanding the metabolism and pharmacokinetics of various chemicals with emphasis on the development of physiologically based pharmacokinetic models that can be used for risk assessment. Currently Dr. Borghoff's research is focused on the developmental pharmacokinetics of estrogen-like compounds such as genistein. CIIT Centers for Health Research is a not-for-profit research institution in which the major core funding is a grant from the American Chemistry Council Long-Range Research Initiative. Other financial support comes from government agencies (U.S. Environmental Protection Agency (USEPA) and NIEHS), independent research organizations, trade associations, and corporations. Dr. Borghoff's research projects have been funded both by the Core research program and through specific research grants from Oxygenated Fuels Association, American Petroleum Institute, American Chemistry Council and ARCO (now Lyondell) Chemical Company. She has recently accepted an opportunity to consult for Huntsman Chemical Company which involves conducting a literature review on what is known on the health effects of methyl tertiary butyl ether.
Dr. Borghoff received the Frank R. Blood Award in 1994 for the best paper of the year published in one of the Society of Toxicology research journals and a Society of Toxicology Risk Assessment Specialty Section Award in 2000. She is currently on the editorial board for *Toxicological Sciences* and *Chemical Biological Interactions*. Dr. Borghoff has served on review panels and as a working group member for National as well as International organizations that include the USEPA, National Cancer Institute, International Programme on Chemical Safety, European Centre for Ecotoxicology and Toxicology of Chemicals, and the International Agency for Cancer Research. She has also been a reviewer for the NIEHS Superfund Basic Research Program Grant (1999) and the Research Grants for the USEPA on Children's Health Issues (1999).

Dr. Timothy Buckley

Dr. Buckley is an Assistant Professor at The Johns Hopkins University, School of Hygiene and Public Health, Department of Environmental Health Sciences, Division of Environmental Health Engineering. He has a joint appointment in the Department of Epidemiology. He was until 1996 an Environmental Scientist at the U.S. Environmental Protection Agency, National Exposure Research Laboratory. There he conceived, designed, and conducted human exposure and biomarker validation studies to support the Agency's risk assessment and regulatory research needs. He also established analytical laboratory to support human exposure research, managed extramural research projects through contracts, grants, and interagency agreements at a level of approximately $1 M/year. Dr. Buckley holds a Ph.D. in Environmental Science from the Rutgers University /Robert Wood Johnson Medical School. He is a Certified Industrial Hygienist - Comprehensive Practice, American Board of Industrial Hygiene. His professional experience focuses on the methods, measurements and models that assess human environmental and occupational exposure. His current efforts are directed toward a combination of community and laboratory research activities. Community studies include the application of exposure assessment in collaboration with communities in order to address particular source (e.g., chemical industry) and health concerns (cancer).

Dr. George Daston

Dr. Daston is a Research Fellow at Procter &Gamble's Miami Valley Laboratories. He holds a Ph.D. in Biology (Teratology) from the University of Miami. Dr. Daston has spent his entire career in research to understand the effects of exogenous chemicals on the developing embryo, fetus and child. His research interests include teratogenic mechanisms, in vitro methodologies, and risk assessment. He has published over 90 peer-reviewed articles, reviews and book chapters, and has edited three books. His most recent research includes 1) toxicantnutrient (especially zinc) and maternal-embryonal interactions in developmental toxicity; 2) the role of pattern formation genes in abnormal development; 3) genomic approaches to endocrine disrupter screening; and 4) improvements in risk assessment methodology for non-cancer endpoints. Dr. Daston's activities in professional societies include serving as Chair of the Reproductive and Developmental Effects Subcommittee of the American Industrial Health Council (1990-99); Chair of the Developmental and Reproductive Toxicology Technical Committee of ILSI-Health Effects Sciences Institute; President (1994-95) of the Society of Toxicology's Reproductive and Developmental Toxicology Specialty Section; President (1999-2000) of the Teratology Society; member of the National Academy of Sciences Board on Environmental Studies and Toxicology (1995-98); and member of EPA's Endocrine Disrupter

Screening and Testing Advisory Committee (EDSTAC). Dr. Daston has recently served on the organizing committees for: ILSI/EPA/AIHC workshops on benchmark dose methodology and human variability in toxic response; an EPA workshop on endocrine-mediated toxicity; and as co-chair of an AIHC/EPA workshop on Leydig cell tumors, an ILSI/EPA workshop on interpreting reproductive toxicity endpoints and a NIEHS workshop on the state of validation of the FETAX assay for teratogen screening. Dr. Daston is an Associate Editor of *Toxicological Sciences*, Field Editor for *Teratogenesis, Carcinogenesis and Mutagenesis*, on the Editorial Board of *Human and Ecological Risk Assessment* and *Reproductive Toxicology,* and an ad hoc reviewer for *Teratology*, *Journal of Nutrition* and other journals. Dr. Daston is an adjunct professor in the Department of Pediatrics and Developmental Biology Program at the University of Cincinnati and Children's Hospital Research Foundation, and lectures in courses on teratology, developmental biology, toxicology, and risk assessment. Dr. Daston was a Visiting Scientist at the Salk Institute, Molecular Neurobiology Laboratory, 1993-94. Dr. Daston was elected a Fellow of AAAS in 1999.

Dr. Paul Foster

Paul Foster is currently a senior research fellow at the National Institute of Environmental Health Sciences studying the mechanisms of abnormal development associated with exposure to endocrine disrupters. Until February of 2002 he was the Director of the research program in endocrine, reproductive and developmental toxicology at the CIIT Centers for Health Research in Research Triangle Park, NC. He joined the Institute in December 1995 after a 13-year career at Zeneca s (formerly Imperial Chemical Industries and now Syngenta) Central Toxicology Laboratory in Cheshire, England, where he was Head of Reproductive and Developmental Toxicology. Dr Foster holds a PhD in biochemistry/ toxicology from Brunel University, Uxbridge UK and conducted his postdoctoral work at the National Foundation for Cancer Research laboratories in the UK. Dr. Foster s research interests span from understanding the potential human health effects of endocrine disrupter; mechanisms of testicular toxicity; the study of early testicular Leydig cell dysfunction induced by chemicals as a prelude to hyperplasia and tumors; the use of rat whole embryo culture techniques for the study of structure - activity
(developmental toxicity) relationships; and toxicokinetic and dynamic parameters affecting the induction of developmental toxicity. Dr. Foster has served on numerous national and international committees (NTP, NIEHS, EPA, WHO, IPCS, ECETOC, OECD, INSERM, MRC, NRC/ NAS, SETAC) dealing with reproductive toxicology and endocrine disruption.

Dr. James Gibson

Dr. Gibson is a Research Professor of Pharmacology and Toxicology at The Brody School of Medicine at East Carolina University. Dr. Gibson holds a Ph.D. in Pharmacology from the University of Iowa. His research interests and experience are in the area of risk assessment, exposure measurement/assessment, dosimetry and mechanism of action, aggregate and cumulative risk and research into various toxicologic endpoints. Dr. Gibson established and managed major research programs at the Chemical Industry Institute of Toxicology. He has also substantial experience in product development and the management of science assessments and regulatory initiatives within the agricultural chemical industry. Dr. Gibson has held the position as President of the Society of Toxicology and served on many editorial boards in the toxicology area.

Dr. Lynn Goldman

Dr. Goldman, a pediatrician and an epidemiologist, is a Professor at the Johns Hopkins University Bloomberg School of Public Health, where her areas of focus are environmental health policy and children's environmental health. She is Director of the Mid Atlantic Public Health Training Center. She co-chairs a school wide response to terrorism threats. Her appointment is in the Department of Environmental Health Sciences with a joint appointment in the Department of Health Policy and Management. In 1993, Dr. Goldman was appointed by the President and confirmed by the Senate to serve as Assistant Administrator (AA) for the EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS). She served in that position for more than five years. As AA for OPPTS she was responsible for the nation's pesticide, toxic substances and pollution prevention laws. Under her watch, EPA expanded right-to-know under the Toxics Release Inventory and overhauled the nation's pesticides laws. Dr. Goldman made significant progress on the issues of testing of high volume industrial chemicals and identification of chemicals that disrupt endocrine systems. At EPA she was successful in promoting children's health issues and furthering the international agenda for global chemical safety. Prior to joining the EPA, Dr. Goldman served in several positions at the California Department of Health Services, most recently as head of the Division of Environmental and Occupational Disease Control. She has conducted public health investigations on pesticides, childhood lead poisoning and other environmental hazards. She has a BS in Conservation of Natural Resources from the University of California, Berkeley, an MPH from the Johns Hopkins University School of Public Health, and an MD from the University of California, San Francisco. She completed pediatric training at Children's Hospital, Oakland, California.

Dr. Goldman has served on numerous boards and expert committees, including the Committee on Environmental Health of the American Academy of Pediatrics, the Centers for Disease

Control Lead Poisoning Prevention Advisory Committee, and numerous expert committees for the National Research Council. She currently is vice chairman of the Institute of Medicine Roundtable on Environmental Health Sciences. She is a member of the IOM Gulf War and Health Study and the National Children's Study Federal Advisory Committee.

Dr. Michael A. Jayjock

Dr. Jayjock is a Senior Research Fellow at the Rohm and Haas Company. He holds an M.S. and Ph.D. from Drexel University. Dr. Jayjock's areas of expertise include: human exposure assessment (specifically modeling contaminant emission source-strength as a function of time, transport and fate indoors); human health risk assessment, integration of estimated dermal and inhalation exposure and dose with estimates of health risk per unit exposure. Dr. Jayjock's research activities include: sources/sinks and backpressure concentration model development for compounds released indoors; and development of techniques for measuring and modeling air-to-lungs, surface-to-skin and air-to-skin exposure. Dr. Jayjock served on the EPA Science Advisory Board's Integrated Human Exposure Committee (IHEC), the National Research Council, Committee on Advances in Assessing Human Exposure to Airborne Pollutants; the National Research Council, Committee on Toxicology – Subcommittee on Risk Assessment of Flame-Retardant Chemicals; and is a member and former Chair of the Human Health Exposure Technical Implementation Panel of the Long Term Research Initiative of the American Chemistry Council. He was on the Program Scientific Peer Review Team, US Environmental Protection Agency, National Exposure Research Laboratory (NERL), Research Triangle Park, NC. His sole support for his research is from the Rohm and Haas Company.

Dr. James Klaunig

Dr. Klaunig is the Director of the State of Indiana, Department of Toxicology and the Director of the Division of Toxicology, Department of Pharmacology and Toxicology at the Indiana University School of Medicine. Dr. Klaunig holds a Ph.D. in Experimental Pathology/Toxicology from the University of Maryland School of Medicine. Dr. Klaunig has served on many advisory bodies at the state and Federal level, as well as editorial boards in his discipline. Dr. Klaunig's expertise is in the area of mechanistic toxicology with a focus on carcinogenicity.

Dr. Amy Kyle

Dr. Kyle holds appointments as a research scientist and lecturer in the Environmental Health Sciences Division of the School of Public Health at the University of California, Berkeley. Dr. Kyle received her Masters of Public Health and PhD in Environmental Health Sciences and Policy from the University of California at Berkeley. Her undergraduate degree in

physical sciences and oceanography was from Harvard University. Her professional affiliations include the American Association for the Advancement of Science, American Public Health Association, Risk Assessment and Policy Association, and Society for Risk Analysis. Her current research focuses on policy responses, including risk assessment, for control of persistent pollutants that accumulate in the global environment; development of environmental health indicators that better describe links between the environment and health and allow for determination of the sustainability of policies and practices; and contaminants in food sources. Dr. Kyle teaches in the environmental health policy program at the School of Public Health at UC Berkeley and is on the faculty of the occupational medicine training program at the University of California at San Francisco. She has taught at the Vermont Law School and recently conducted sessions on risk assessment for the National Association of Attorneys General national conference and the Western States Enforcement Project for representatives of 13 states and two Canadian provinces. Dr. Kyle has published work on risk assessment, management of pesticides, development of environmental health indicators, comparative risk assessment, use of risk assessment in environmental policy in the US, international policy for hazardous waste remediation, and policy implications of different methods for assessing the health significance of hazardous waste sites. Dr. Kyle also works as a consulting scientist on environmental science and policy issues for states and non-governmental organizations. She was awarded a Switzer environmental leadership award to work with the Natural Resources Defense Council on an analysis of the scope and public health significance of contaminants in fish. She is currently working with the State of California Department of Health Sciences on guidelines for risk assessment for electric and magnetic fields. She serves on an advisory committee for the organization Toxicity Excellence in Risk Assessment on a project comparing risks and benefits of consumption of fish. Dr. Kyle served for five years as Deputy Commissioner for the Alaska Department of Environmental Conservation and has practical experience with the Exxon Valdez and other oil and hazardous substance spills and associated cleanup issues. She worked on both state and national legislation on oil and hazardous substances spills, including the Oil Pollution Act of 1990 and several pieces of state legislation. Before that, she was executive director of the Alaska Coastal Management Program. She has also worked in the Alaska Governor's office on environmental and resource policy issues including federal policy for oil and hazardous substance spills and coastal resource management.

Dr. George Lambert

Dr. Lambert is an Associate Professor of Pediatrics and Associate Director of the Clinical Research Center at the UMDNJ-Robert Wood Johnson Medical School. He holds a MD degree

from the University of Illinois and has had post graduate training in: Clinical Research in Neonatology, has been an Intern and Resident at the Harriett Lane Home, Johns Hopkins Hospital, Baltimore, Md, He was also a Pharmacology Fellow at Children's Hospital of Philadelphia, PA. Dr. Lambert is certified by the American Board of Pediatrics, 1979 & 1980; Neonatal/Perinatal Medicine, 1980 and as an Instructor, Neonatal Resuscitation, 1989

Dr. Lambert is a member of the Environmental and Occupational Health Sciences Institute (EOHSI), UMDNJ-Robert Wood Johnson Medical School and an Adjunct Associate Professor of Pharmacy in the College of Pharmacy of Rutgers, The State University of New Jersey. He is also a member of the Cancer Institute of New Jersey, and Director of the Center for Child and Reproductive Environmental Health, Director, NIH / USEPA Center for Childhood Neurotoxicology and Exposure Assessment, and the Director, Pediatric Clinical Research Center, UMDNJ- Robert Wood Johnson Medical School.

Dr. Lambert has served as a consulting expert to a number of professional and governmental organizations including: the Neuropharmacology Division of FDA, the U.S. Congress, TSCA Interagency Testing Committee, Department of Energy, Oakridge National Laboratory, Division of Chemical Assessment, Office of Orphan Products Development, FDA; NICHD's National Neonatal Collaborative Project. He is a Member, Committee on Drugs, American Academy of Pediatrics, (National Committee), a Member - Human Health Effects Committee of the Joint (U.S. and Canadian) Commission on the Great Lakes, a consultant to the World Health Organization, Environmental Toxicology in Children. He has served on a number of US EPA Science Advisory Board panels including the Dioxin Reassessment Panel. Dr. Lambert is a Fellow of the American Academy of Pediatrics

Dr. Lambert's grants include: Since 1998: New York Health Department NIEHS Award; NIEHS/US EPA Superfund Center, Co-Investigator - Mohawk Project; NIEHS Center of Excellence (M. Gallo, PI); NIEHS training Grant in Toxicology (K Reuhl, PI); US EPA - Effect of *in utero* exposure to PCB's on Sexual Maturation' NJ DHHS / CDC - Hypospadism and Xenoestrogen exposure in humans; NIEHS- Pharmacogenetics of environmental chemical related toxicities (JY Hung, PI); Cancer Commission of New Jersey – Effects of Herbal products on sex hormone synthesis and metabolism; NJ Department of Environmental Protection – Effects of Eating Newark crabs on human health; NIEHS / USEPA Children Center for Environmental Health and Disease Prevention- Center for Childhood Neurotoxicology and Exposure Assessment; NCI Program Project: Tea Cancer Chemoprevention (PI CS Yang); NIEHS – The Effects of World Trade Center on human health (PI M. Gallo --Dr Lambert's Project: The effects of WTC on Reproductive Outcome.)

Dr. Joseph Landolph

Dr. Landolph is Associate Professor of Molecular Microbiology and Immunology and Pathology at the Keck School of Medicine, University of Southern California. He also serves as Associate Professor of Pharmacology and Toxicology at the USC School of Pharmacy. Dr. Landolph holds a PhD in Chemistry from the University of California - Berkeley and has done postdoctoral training in cancer mechanisms at the University of Southern California Comprehensive Cancer Center. Dr. Landolph's research interests are in molecular mechanisms and molecular biology of cell transformation and carcinogenesis induced by metals and PAHs, oxygen radicals in neoplastic cell transformation, genetic toxicology, and the molecular biology of human lung and prostate cancer. Dr. Landolph served on the California Carcinogen Identification Committee of the Science Advisory Board for California EPA.

Dr. Philip Landrigan

Dr. Landrigan, M.D., M.Sc. is a pediatrician and the Ethel H. Wise Professor and Chair of the Department of Community and Preventive Medicine of the Mount Sinai School of Medicine in New York City. He holds a Professorship in Pediatrics at Mount Sinai. He directs the Mount Sinai Center for Children's Health and the Environment. Dr. Landrigan obtained his medical degree from the Harvard Medical School in 1967. He interned at Cleveland Metropolitan General Hospital. He completed a residency in Pediatrics at the Children's Hospital Medical Center in Boston. He obtained a Master of Science in occupational medicine and a Diploma of Industrial Health from the University of London. From 1970 to 1985, Dr. Landrigan served as a commissioned officer in the United States Public Health Service. He served as an Epidemic Intelligence Service Officer and then as a medical epidemiologist with the Centers for Disease Control in Atlanta. While with CDC, Dr. Landrigan served for one year as a field epidemiologist in El Salvador and for another year in northern Nigeria. Dr. Landrigan is a member of the Institute of Medicine of the National Academy of Sciences. He is Editor-in-Chief of the *American Journal of Industrial Medicine* and previously was Editor of *Environmental Research*. He has chaired committees at the National Academy of Sciences on *Environmental Neurotoxicology* and on *Pesticides in the Diets of Infants and Children.* Dr. Landrigan's report on pesticides and children's health was instrumental in securing passage of the Food Quality Protection Act of 1996, the major federal pesticide law in the United States. In New York City, he served on the Mayor's Advisory Committee to prevent Childhood Lead Paint Poisoning and on the Childhood Immunization Advisory Committee. He is Chair of the New York State Advisory Council on Lead Poisoning Prevention. From 1995 to 1997, Dr. Landrigan served on the Presidential Advisory Committee on Gulf War Veteran's Illnesses. In 1997 and 1998, Dr.

Landrigan served as Senior Advisor on Children's Health to the Administrator of the U.S. Environmental Protection Agency. He was responsible at EPA for helping to establish a new Office of Children's Health Protection.

Dr. Steve Lewis

Dr. Lewis is currently a Distinguished Scientific Associate at ExxonMobil Biomedical Sciences, Inc. Dr. Lewis holds a Ph.D. in Toxicology from Indiana University School of Medicine. His areas of expertise include the general toxicology; toxicology of petroleum and petrochemicals, with specific emphases on benzene, alkylated single-ring aromatics, hexanes, and polynuclear aromatics. He also has experience with qualitative and quantitative risk/safety assessment for cancer and non-cancer effects; quantitative risk/safety assessment for cancer and non-cancer health hazards; application of research and testing data to develop occupational and ambient exposure guidelines. Dr. Lewis has served on the editorial boards for a number of scholarly journals (Associate Editor, NONLINEARITY in BIOLOGY, TOXICOLOGY and MEDICINE, Chemical Rubber Company Press; REGULATORY TOXICOLOGY and PHARMACOLOGY; TOXICOLOGY; and NEUROTOXICOLOGY.

Dr. Abby Li

Dr. Abby Li received her Ph.D. from the University of Chicago in pharmacology and physiology. She is a Senior Science Fellow at Monsanto and is a toxicologist in the Department of Toxicology and Human Health Risk Assessment. Dr. Li has product stewardship responsibilities involving general toxicology, exposure and risk assessment. She was Monsanto's Neurotoxicology Team Leader responsible for developing a research program to study effects of pharmaceuticals, pesticides, and industrial chemicals on motor activity, schedule-controlled operant behavior, functional observational battery, auditory startle habituation, learning and memory, and neuropathology. In addition to her research in neurotoxicology, she has also conducted *in vivo* pharmacokinetic studies (ADME studies) and *in vitro* metabolism studies. Dr. Li served on the US Expert Team to develop international OECD guidelines on neurotoxicity (1995 - 1998) and developmental neurotoxicity (1996-2000). Dr. Li was the Chair (2000-2002) of the Neurotoxicology Technical Panel of the American Chemistry Council's Long Range Initiative (ACC LRI) responsible for funding research to advance the field of neurotoxicology in focus areas of susceptible populations and development of new methods for hazard and exposure assessment. She served as Co-Chair of Crop Life America's Developmental Neurotoxicology Working Group in 2000 and is currently a member of this group. Dr. Li served on the Editorial Board of Neurotoxicology from 1995-2001 and is a member of the scientific committee for the 9th International Neurotoxicology Association meeting (2002-2003). She is a

member of the EPA's Science Advisory Board's Environmental Health Committee and reviewed the EPA's 1999 draft cancer guidelines, the RfC Methods Case Studies, and the Lead 403 Rule. Dr. Abby Li was also a peer consultant to the September 10-11, 1996 EPA Benchmark Dose Peer Consultation.

Dr. George Lucier

Dr. Lucier is retired as the Director, Environmental Toxicology Program, at the National Institute of Environmental Health Sciences (NIEHS). In that previous capacity he established new directions for the National Toxicology Program, the nation's most comprehensive toxicology testing program. He also serves as Chairman of the Scientific Advisory Board for regulation of toxic air pollutants by the State of North Carolina. Dr. Lucier was a researcher at NIEHS beginning in 1970. His research group focused on molecular epidemiology and dosimetry. His recent work used fundamental knowledge to reduce uncertainty in risk estimates of endocrine disrupting chemicals. He is widely recognized for his work in the areas of steroid action, mechanisms of dioxin toxicity, and xenobiotic metabolism, and has published more than 200 articles in these areas. During the last 10 years, he has helped to forge the emerging areas of molecular epidemiology and the development of laboratory approaches to improve the risk assessment process and in this capacity, he frequently advises Federal and state agencies on high visibility human health risk assessments. He received his Ph.D. from the School of Agriculture, University of Maryland, College Park. He also serves as Co-Editor-in-Chief of Environmental Health Perspectives.

Dr. Michael McGeehan

Dr. McGeehin is the Director of the Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention. Dr. McGeehin holds a PhD in Environmental Health (Epidemiology) from Colorado State University. His area of expertise is in environmental epidemiology (study design, modeling, analysis), health outcome surveillance, exposure assessment, statistical analysis; disease cluster investigations. His research activities have included research on drinking water DBPs and bladder cancer; linkage of health and environmental databases; childhood lead poisoning; environmental health surveillance; heat-related morbidity and mortality; climate change health effects; and environmental health indicators. Dr. McGeehin has served on other advisory committees, professional societies, including service as Co-chair of the Human Health Sector for the U.S. National Assessment Team; Director of the WHO Collaborating Center for Environmental Epidemiology; the National Advisory Committee of the Natural Hazards Research Center, the Society for Epidemiologic Research; the EPA Drinking Water Contaminant

Candidate Working Group; and the IOM Environmental Working Group – Health Indicators Project.

Dr. Gunter Oberdorster

Dr. Oberdorster is a Professor of Toxicology, Head of the Division of Respiratory Biology and Toxicology, and Director of the UR-EPA Particulate Matter Center at the University of Rochester. Dr. Oberdorster holds DVM and Ph.D. degrees from the University of Giessen. His research interests have focused on airborne particulates and their related toxicity as well as other pulmonary disease conditions. Dr. Oberdorster has served as President of the Society of Toxicology Inhalation Specialty Section and Chaired many symposia, workshops, and meetings, nationally and internationally, on pulmonary toxicology issues. He has also served on numerous advisory committees in the respiratory toxicology area for the EPA, WHO, IARC, ILSI, NIOSH, NIEHS, API, DOE, and many others. He is a member of the NRC Board of Toxicology and also served on the NRC Committee on Research Priorities for Airborne Particulate Matter. He is also a member of the EPA Clean Air Science Advisory Committee.

Dr. Carey Pope

Dr. Pope obtained a Bachelor's (1976) and Master's (1979) degree in Biology from Stephen F. Austin State University in Nacogdoches, Texas. He received a Ph.D. in Pharmacology and Toxicology from the University of Texas Graduate School of Biomedical Sciences in Houston in 1985. Dr. Pope was a postdoctoral associate in the Neurology Department at Baylor College of Medicine (1986) and a National Research Council (NRC) research associate at the U.S. Environmental Protection Agency's Health Effects Research Laboratory in Research Triangle Park, NC (1986-1989). He was Assistant (1989-1993), Associate (1993-1998) and full Professor (1998-1999) of Toxicology at the University of Louisiana College of Pharmacy before joining the faculty of College of Veterinary Medicine at Oklahoma State University as Professor and Sitlington Endowed Chair in Toxicology (2000-present). Dr. Pope's research has focused on mechanisms of toxicity of and adaptation to anticholinesterases. Areas of interest include the influence of age (maturation and aging) on sensitivity to organophosphorus compounds, how physical and chemical stressors may modify neurotoxicity, dietary influences on organophosphate toxicity, and mechanisms of interactive toxicity with multiple anticholinesterase exposures. He has been an ad-hoc member of the Scientific Advisory Panel under FIFRA since 1988, a member of the Food Quality Protection Act Board since 1996, a consultant to the Special Assistant to the Secretary of Defense for Gulf War Illnesses in 1997, and was recently selected as a member of the NRC Subcommittee on Toxicologic Assessment of Low-Level Exposures to Chemical Warfare Agents. Dr. Pope is

currently President-elect of the International Neurotoxicology Association and Vice President of the Neurotoxicology Section of the Society of Toxicology.

Dr. Lorenz Rhomberg

Dr. Rhomberg is a Principal at Gradient Corporation. Dr. Rhomberg holds a Ph.D. in Biology from SUNY Stony Brook. His areas of expertise include risk assessment, toxicology, pharmacokinetics, chlorinated solvents, endocrine active agents. Dr. Rhomberg's consulting practice includes evaluation of chemical toxicity, review and conduct of qualitative and quantitative risk assessment; regulatory guideline issues; dose-response modeling and cross-species extrapolation issues; physiologically based pharmacokinetic modeling and its use in risk analysis; and aggregate exposure and cumulative risk issues. His work has a special emphasis on cancer and chronic noncancer toxicity, chlorinated solvents, and assessment of endocrine active agents. Prior to affiliating with Gradient Corporation Dr. Rhomberg was an Assistant Professor of Risk Analysis, Department of Health Policy and Management and Department of Environmental Health at Harvard University and before that he was a Biostatistician (Health Risk Assessment) at the US EPA. Dr. Rhomberg was on the National Academy of Sciences, COT Subcommittee on Manufactured Vitreous Fibers, a Consultant to the Presidential/ Congressional Commission on Risk Assessment & Management, an *Ad hoc* member of the FIFRA Scientific Advisory Panel (EPA) (1997, 1999, 2000); and many other expert groups. He has supported projects for the American Chemistry Council (Principle Investigator: "Species Differences in Biological Parameters and their Role in Extrapolating Biologically Based Carcinogenesis Models from Animals to Humans"--ongoing); The Port of Portland Oregon (reviewed existing standards for air toxics exposures and analysis of potential for health impact on populations surrounding Swan Island Shipyard); Health Canada (Principle Investigator. Framework for developing data-based distributional approaches to noncancer risk assessment); the U.S. EPA, National Center for Environmental Assessment (Commissioned report and manuscript on dose-response analysis using pharmacokinetic model results on data from carcinogenicity studies of trichloroethylene in animals); the Chemical Industry Institute of Toxicology (Led meeting and contribute to manuscript on alternative approaches to physiologically based pharmacokinetic modeling of 1,3-butadiene); the National Research Council (Principle Investigator. Led 2-year project on developing a risk assessment framework for protecting the health of U.S. forces deployed in hostile environments); and the Chemical Manufacturers Association (Principle Investigator. Developed data-based approaches to a distributional analysis of reproductive and developmental toxicity of ethylene oxide, leading to a distributed reference concentration).

Dr. Beate Ritz

Dr. Ritz is an Associate Professor in the Department of Epidemiology in the UCLA School of Public Health. Dr. Ritz holds MD and Ph.D. degrees from the University of Hamburg as well as a Ph.D. in Epidemiology from UCLA. Dr. Ritz's major discipline is occupational and environmental epidemiology. Her major research interests are occupational and environmental health issues, radiation and cancer, air pollution and birth outcomes (such as low birth weight, pre-term birth and malformations); pesticide health effects (such as adult pesticide exposure and Parkinson's disease) and the health effects of reclaimed water use. She teaches classes in occupational and environmental epidemiology and on policy issues.

Dr. Herbert Rosenkranz

Dr. Rosenkranz is a Professor of Environmental and Occupational Health at the Graduate School of Public Health, University of Pittsburgh; a past Chairman of the Department of Environmental and Occupational Health, Graduate School of Public Health, University of Pittsburgh. He is also a Professor of Pharmacology, School of Medicine, University of Pittsburgh, and a Research Professor of Biomedical Sciences, Florida Atlantic University, Boca Raton, FL Dr. Rosenkranz holds a Ph.D. from Cornell University. Dr. Rosenkranz has been active in the field of computational toxicology since 1984, and has since become an internationally recognized leader in the field of computational toxicology. He has served on the editorial boards of leading academic journals in this field, including Toxicology Modeling (1994-1997) and SAR QSAR in Environmental Research (1998-present), and has authored or coauthored dozens of scientific studies involving the development and use of (quantitative) structure-activity relationship, or (Q)SAR, models to examine a wide range of human health and environmental effects. Dr. Rosenkranz has served as a consultant to the EPA since 1977, and in this capacity, has become intimately familiar with EPA guidelines and risk assessment procedures. He is also a former member of the Presidential Panel on Health and Environmental Effects of Advancement of Energy Technologies (1978-1980) and the EPA's Scientific Review Panel for Health Research (1980-1993). Dr. Rosenkranz has served since 1978 as a member of the International Commission for Protection Against Environmental Mutagens and Carcinogens, since 1980 as a consultant to the International Agency for Research on Cancer, and since 1984 as chair of the IARC Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. He has also served on a number of high-level advisory committees, including the National Cancer Institute Panel on Carcinogenicity and Mutagenicity (1976-1981), the National Academy of Sciences/National Research Council Committee on the Carcinogenicity of Cyclamates (1984-1985), and the Consumer Product Safety Commission Chronic Hazard

Evaluation Panel (1984-1985), to name only a few.

Dr. Jennifer Sass

Dr. Sass is a Senior Scientist at the Natural Resources Defense Council. She has spent over a decade as a laboratory researcher, in biomedical research. Her areas of study include neurobiology, cell and molecular biology, and toxicology. Research specifics include the study of mercury on neural development, the study of aluminum on neurobiochemistry, and the study of stress proteins (chaperones) in embryonic development. Her Ph.D. was completed in 1998, from the University of Saskatchewan, in the Dept. of Anatomy and Cell Biology. Her postdoctoral research was completed in 2000, at the University of Maryland, Baltimore, in the Program of Human Health and the Environment. Dr. Sass was a member of the Expert Peer Review for the *Draft Framework for Cumulative Risk Assessment* document, US EPA (2001); a member of the Roundtable Workshop to discuss Genomics and Environmental Policy, organized by the Woodrow Wilson International Center for Scholars, Washington, DC. (2002); a member of the EPA Pesticide Program Dialogue Committee (PPDC) (ongoing), to provide feedback to the pesticide program on various pesticide regulatory, policy and program implementation issues and a member of the CARAT (ongoing), an EPA -U.S. Department of Agriculture joint advisory committee (Committee to Advise on Reassessment and Transition, CARAT) to provide advice on strategic approaches for pest management planning, transition, and tolerance reassessment for pesticides as required by the Food Quality Protection Act (FQPA). Dr. Sass works primarily on following the EPA assessment and regulation of pesticides and toxic industrial chemicals. This has included chemicals such as atrazine, malathion, endosulfan, the cumulative risk assessment of the organophosphorus pesticides, styrene, butadiene, trichloroethylene, and vinyl chloride. In addition, she is actively working with other public interest groups to enforce governmental policies limiting researchers with financial conflicts of interest from participating as independent scientists, on governmental advisory committees.

Dr. Robert Spengler

Dr. Spengler is Associate Administrator for Science at the Agency for Toxic Substances and Disease Registry (ATSDR). He has worked for ATSDR since 1991 and was the Assistant Director for Science, Division of Health Studies, until 1998. His previous positions include directing environmental and chronic disease epidemiology programs in state health departments of Vermont and Illinois and academic appointments at McGill University, University of Toronto, University of Illinois at Chicago, and Southern Illinois University.

Dr. Jed Waldman

Dr. Waldman is Chief of the Indoor Air Quality Section, California Department of Health

Services, Environmental Health Laboratory Branch, Berkeley, CA. He is also a Principal investigator at the Public Health Institute, Berkeley, CA and an Adjunct Associate Professor at the UMDNJ-Robert Wood Johnson Medical School, Dept. Environmental & Community Med., Piscataway, NJ. Dr. Waldman holds a Ph.D. in Environmental Engineering Science (Atmospheric Chemistry) from the California Institute of Technology. His area of expertise is in exposure assessment, environmental tobacco smoke, radon, combustion appliances, building product emissions, ozone-generators; and environmental quality in schools. His research activities have included: data analyses of the U.S. EPA BASE study results on bioaerosols the dynamics of environmental tobacco smoke (ETS) in offices, emissions testing of building materials with high-recycled contents, environmental conditions in public school classrooms, and residential and school classroom exposures to radon in California. Dr. Waldman is a member of the US EPA Science Advisory Board's Integrated Human Exposure Committee, Member, 2000-02, the California Interagency Working Group on Indoor Air Quality, Chair, 1986-present, and the International Society of Exposure Assessment, Board of Councilors, 1999-2002. Sources of recent grant and/or contract support come from the California Environmental Protection Agency, the Tobacco-Related Disease Research Program (University of California), the U.S. EPA and the U.S. OSHA

Dr. Bernard Weiss

Dr. Weiss is Professor of Environmental Medicine and Pediatrics at the University of Rochester School of Medicine and Dentistry, where he has been a member of the faculty since 1965. Before coming to Rochester, he served on the faculty of the Johns Hopkins School of Medicine, and, earlier, held an appointment at the U.S. Air Force School of Aviation Medicine. Dr. Weiss has served as a member of many committees and panels devoted to toxicology and environmental health, including those organized by the U.S. Environmental Protection Agency's Science Advisory Board, and the National Academy of Sciences. He is especially concerned with risk assessment issues arising from the effects of environmental chemicals on brain development and brain aging. He is the editor or co-editor of seven books and monographs and author or co-author of over 200 articles. His special interests and publications lie primarily in areas that involve chemical influences on behavior; these include the neurobehavioral toxicology of metals such as lead, mercury and manganese; endocrine disrupter such as dioxin; solvents such as toluene and methanol; drugs such as cocaine; and air pollutants such as ozone.

Attachment 3: List of the Names of Groups and Individuals Submitting Public Comment on the HHRS Short List

1. Steve Gurney, Geologist, Natural Resources Defense Council

2. Rick Blum, Senior Researcher, Integrity in Science Center for Science in the Public Interest

Attachment 4: Questions Posted to Short List Candidates about Their "Points of View" and Relationship to the Review Material to Be Considered by the Panel

1. Have you had any previous involvement with the review document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify that involvement.

2. Have you served on previous advisory panels or committees that have addressed the topic under consideration? If so, please identify those activities.

3. Have you made any public statements (written or oral) on the issue? If so, please identify those statements.

4. Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

Attachment 5

U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Human Health Research Strategy Review Panel*

CHAIR

Dr. James E. Klaunig, Professor and Director, Department of Pharmacology and Toxicology, School of Medicine , Indiana University , Indianapolis, IN

Also Member: Environmental Health Committee

OTHER SAB MEMBERS

Dr. George Lambert, Associate Professor and Center Director, Center for Child and Reproductive Environmental Health, Environmental and Occupational Health Sciences Institute, Robert Wood Johnson Medical School/ University of Medicine and Dentistry of New Jersey, Piscataway, NJ

Member: Environmental Health Committee

Dr. Joseph Landolph, Associate Professor of Molecular Microbiology & Immunology, Pathology, and Molecular Pharmacology & Toxicology, Cancer Research Laboratory, Keck School of Medicine, University of Southern California, Los Angeles , CA

Member: Drinking Water Committee

Dr. Randy Maddelena, Scientist, Environmental Energy Technologies Division, Indoor Environment Department, Lawrence Berkeley National Laboratory, Berkeley, CA

Member: Integrated Human Exposure Committee

Dr. Maria Morandi, Assistant Professor of Environmental Science & Occupational Health,

School of Public Health, University of Texas - Houston Health Science Center, Houston, TX
Member: Research Strategies Advisory Committee

CONSULTANTS

Dr. Paul Blanc, Professor, Division of Occupational and Environmental Medicine, University of California San Francisco, San Francisco, CA

Dr. James E. Gibson, Research Professor of Pharmacology and Toxicology, Department of Pharmacology and Toxicology, The School of Medicine at, East Carolina University, Greenville, NC

Dr. Michael Jayjock, Research Fellow, Toxicology Department, Rohm and Haas Co., Spring House, PA

Dr. Steven C. Lewis, Distinguished Scientific Associate, Toxicology and Environmental Sciences , Exxon Mobil Biomedical Sciences, Inc., Annandale, NJ

Dr. Beate Ritz, Associate Professor, School of Public Health, UCLA, Los Angeles, CA

Dr. Herbert Rosenkranz, Dr., Biomedical Sciences 140 BC, Florida Atlantic University, Boca Raton, FL

Dr. Bernard Weiss, Professor, Department of Environmental Medicine, University of Rochester Medical Center, Rochester, NY

FEDERAL EXPERTS

Dr. Robert Spengler, Associate Administrator for Science, Agency for Toxic Substances and Disease Registry, Atlanta, GA

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* Members of this SAB Panel consist of (a) SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees. (b)SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue. (c) Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board. (d) Federal Experts: "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.